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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,062	02/28/2002	Joseph M. Jilka	P04532US1	3714

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DES MOINES, IA 50309-2721

EXAMINER

EPFS FORD, JANET L

ART UNIT PAPER NUMBER

1635

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/086,062

Applicant(s)

JILKA ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,8-19,27-36 and 40-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44 and 45 is/are allowed.
- 6) ☒ Claim(s) 1,8-19,27-36 and 40-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 11-17-04
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Interview Summary***

1. During a discussion with Applicant's representative, on November 17, 2004, the examiner agreed that the Notices of Non-compliant Amendment mailed 5/18/2004 and 9/23/2004 in response to Applicant's amendment to the claims filed 3/01/2004 and 7/16/04, respectively, were improper since the Examiner did not consider the preliminary amendment to the claims submitted by Applicants on August 14, 2002. Applicants amendment to the claims submitted on 3/01/2004 were based upon the claims as amended in the preliminary amendment, and not based upon the claims as originally filed.

### ***Specification***

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 21, 2<sup>nd</sup> ¶.

### ***Response to Amendment***

3. It is noted that claims 2-7, 20-26, and 37-39 were cancelled in the Preliminary Amendment submitted by Applicants. Therefore, any prior rejections of these claims are withdrawn.

4. The Declaration filed on 11-22-04 under 37 CFR 1.131 has been considered but is ineffective to overcome the rejection of claims 1, 8, 13-19, 27, 32-36 and 40 over the Goldsbrough et al. reference. According to MPEP § 715.04, all the inventors of the subject matter claimed may make an affidavit or declaration under 37 CFR 1.131. In the instant case, the Declaration submitted by Applicants was only signed by Joseph Jikla. However, Applicant's

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Declaration does not comply with MPEP § 715.04 [R-2](a), since there is no evidence on record indicating that Joseph Jikla is the sole inventor of the claimed subject matter, or that he qualifies under 37 CFR 1.42, 1.43, or 1.47. The instant application also names Elizabeth Hood and John Howard as inventors, yet there is no evidence that all of the named inventors are not also inventors of every claim of the application. The Jikla declaration does not even mention the names of the co-inventors of the instant application. Moreover, according to MPEP § 715.04[R-2] even though the declaration was signed by fewer than all the joint inventors, the declaration must show completion of the invention by all of the joint inventors of the subject matter of the claim(s) under rejection.

*Response to Arguments*

*Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1, 8, 13-19, 27, 32-36, and 40 remain rejected under 35 U.S.C. 102(a) as being anticipated by Goldsbrough et al. (WO00/15810 A1), for the reasons of record set forth in the prior Office Action.

7. Applicant's arguments filed 11-22-04 have been fully considered but they are not persuasive. Applicants traverse the instant rejection by way of submitting a Declaration by Joseph Jikla, which Applicants argue establishes conception and reduction of practice of the invention in the United States prior to the International Publication date of the cited application.

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The Jikla declaration demonstrates possession of ubiquitin promoters that contain a deletion of the heat shock elements prior to the international Publication date of Goldsbrough et al. However, the Jikla declaration does not show completion of the invention by all of the joint inventors of the subject matter of the claims under rejection. Therefore the Jikla declaration is insufficient to overcome instant rejection over Goldsbrough et al. As stated in the prior Office Action, the Goldsbrough et al. reference describes the construction of plant expression constructs (pPBI97-2BdUN1 & pPBI92-2BdUN1), and methods of using these constructs for the expression of genes in plant tissues. The constructs comprise a reconstituted ubiquitin regulatory system comprising a modified ubiquitin promoter that lacks the two overlapping heat shock consensus sequence elements (page 32, 2<sup>nd</sup> paragraph).

8. It is noted that the instant rejection is maintained over claim 8, although the claimed subject matter set forth in the claim is unclear since the position of -214-- -190 as it corresponds to SEQ ID NO: 1 is not sufficiently defined. However, to the extent that the claim 8 may encompass wherein the sequence of the two overlapping heat shock elements correspond to SEQ ID NO: 1, the instant rejection is maintained.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 8 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites “[T]he promoter sequence of claim 1 wherein said sequence includes a deletion of two overlapping heat shock elements at position -214– -190 of SEQ ID NO: 1. However, SEQ ID NO: 1 is only 25 nucleotides in length, it is unclear what nucleotide sequence corresponds to position -214– -190 of SEQ ID NO: 1. Due to the ambiguity associated with position -214– -190 of SEQ ID NO: 1, the substance of the actual claimed invention is uncertain.

Claim 43 recites “[T]he promoter sequence of claim 44, wherein said Ps1 element is a trimer.” There is lack of antecedent basis for the term “said Ps1 element” in claim 44. Moreover, claim 43 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a *previous claim*. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 8-19, 27-36, 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldsbrough et al. (WO00/15810 A1) in view of Pater et al. (The Plant Cell, Vol. 5, pages 877-886, August 1993).

13. The discussion of Goldsbrough et al. as set forth above and as set forth in the Office Action mailed 11-28-2003, are incorporated here. As stated previously, Goldsbrough et al. describe the construction of plant expression constructs (pPBI97-2BdUN1 & pPBI92-2BdUN1),

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and methods of using these constructs for the expression of genes in plant tissues. The constructs comprise a reconstituted ubiquitin regulatory system comprising a modified ubiquitin promoter that lacks the two overlapping heat shock consensus sequence elements (page 32, 2<sup>nd</sup> paragraph). The constructs of Goldsbrough et al. are designed to be tissue-specific, and will desirably cause expression of operably linked sequences at substantial levels only in the tissue of the plant where starch synthesis and/or starch storage mainly occurs (page 12, 1<sup>st</sup> ¶). This reference also teaches that starch is the major form of carbon reserve in plants, constituting 50% or more of the dry weight of many storage organs, e.g. tubers, and seeds (see page 1, last ¶). However, Goldsbrough et al. does not teach ubiquitin promoters comprising Psl elements.

Pater et al. teach that the addition of a trimer of a 22 base pair region of the Psl promoter containing TGAC-like motifs to a heterologous minimal promoter conferred high reporter gene expression in the seed of transgenic tobacco (see page 879, last ¶ and Figure 4). The 22 base pair region from the Psl promoter is described by Pater et al. as playing an essential role in the seed-specific expression pattern of the Psl gene (see abstract). The 22 base pair sequence of Pater et al. has the same sequence as that shown for SEQ ID NO: 5 of the instant application (see Figure 2).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the teachings of Goldsbrough et al. in view of Pater et al. to make the instantly claimed invention. One of skill in the art at the time of the instant invention would have been motivated to modify the promoters of Goldsbrough et al. with the Psl TGAC-like motifs of Pater et al. One of skill in the art at the time of the instant invention would have been motivated to make this modification because the constructs of Goldsbrough et al. are preferably designed to

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provide tissue specific expression in the storage organs of plants, including tubers and seeds, and the Ps1 elements of Pater et al. are known in the art to confer a high level seed specific gene expression of heterologous sequences.

*Conclusion*

14. Claims 44-45 are free of the prior art searched and of record.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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